



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

HIV Study in Blood Donors from Five Chinese Regions

SUMMARY: In compliance with the requirement of Section 3506(c) (2) (A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the

data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Simone Glynn, MD, Project Officer/ICD Contact, Two Rockledge Center, Suite 9142, 6701 Rockledge Drive, Bethesda, MD 20892, or call 301- 435-0065, or E-mail your request, including your address to: glynnsa@nhlbi.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: HIV Study in Blood Donors from Five Chinese Regions, 0925-0596 reinstatement with change, National Heart, Lung and Blood Institute (NHLBI)

Need and Use of Information Collection: This Study is a reinstatement of OMB Number: 0925-0596 expiration date, January 31, 2012. To better understand the diversifying and changing Human Immunodeficiency Virus (HIV) epidemic, and contemporary HIV risk factors, especially those associated with recent HIV infections, this HIV risk factor study in China is proposed as part of the Recipient Epidemiology and Donor Evaluation Study-III (REDS-III). The major objectives of the study will be to evaluate the proportion of blood donors in China who test positive for HIV and have acquired their infection recently or more remotely; the risk of releasing a blood product that contains HIV (HIV residual risk); and the risk factors associated with HIV infection in China. The study will also assess the frequency of distinct HIV-1 viral lineages and drug resistant mutations among HIV-positive blood donors. In 2011, there were 780,000 people infected with HIV in China and it is estimated that over 300,000 HIV infected people in China are not aware of their infection status. The large migrating population and the

complexity of HIV transmission routes in China make it difficult to implement a comprehensive and effective national HIV control strategy. Risk factors for infections can change over time; thus, identifying factors that contribute to the recent spread of HIV in a broad cross-section of an otherwise unselected general population, such as blood donors, is highly important for obtaining a complete picture of the epidemiology of HIV infection in China. Because the pace of globalization means infections can cross borders easily, the study objectives have direct relevance for HIV control in the US and globally. Recent years have seen an increase in blood donations from repeat donors in most Chinese regions. This increase permits longer-term follow-up and testing of repeat donors which allow for calculation of new HIV infection rates and residual risks. The HIV data, for both recently and remotely acquired infections, from the proposed study will complement existing data on HIV risks obtained from general and high risk populations to provide comprehensive HIV surveillance data for China. This study will also monitor genetic characteristics of recently acquired infections through genotyping and drug resistance testing, thus serving a US and global public health imperative to monitor the genotypes of HIV that have recently been transmitted. For HIV, the additional monitoring of drug resistance patterns in newly acquired infection is critical to determine if currently available antiretroviral medicines are capable of combating infection. Genotyping and host response information are scientifically important not only to China, but to the US and other nations since they provide a broader global understanding of how to most effectively manage and potentially prevent HIV, for example through vaccine development. Efforts to develop vaccines funded by the National Institutes of Health and other US-based organizations may directly benefit from the findings of this study.

Blood donors are tested for transfusion-transmissible infections including HIV when they

present to donate, and test result information as well as demographic data will be routinely collected in a database at the five blood centers participating in REDS-III studies (located in the cities of Chongqing, Liuzhou, Luoyang, Mianyang, and Urumqi). These data will allow for calculation of HIV incidence, prevalence, and residual risk. Additionally, a case-control study will be conducted over a 2 and 1/2 year period to evaluate the risk factors associated with HIV infection among blood donors. Cases will be defined as potential donors who deny risks on the donor screening questionnaire but are found to be positive on HIV testing (their donation is discarded). HIV-positive donors who gave blood at one of the five blood centers as stated above (primary sites) or at blood centers located in the Guangxi Autonomous Region (peripheral sites, recruited through the Guangxi CDC for this study only but not other REDS-III studies) will be eligible to participate and complete a Risk Factor Questionnaire that will assess general demographic and risk factor information pertinent to HIV infection. Controls will be negative for HIV on confirmatory testing. Assuming 50% response rate, it is anticipated that 390 HIV-positive donors and 960 controls will participate in the case control study. The results of this study will contribute to global HIV surveillance and prevention, provide a broader global understanding of HIV epidemiology, and support public health efforts to most effectively manage and potentially prevent HIV transmission both worldwide and in the US.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 450.

Estimated Annualized Burden Hours

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours

HIV Risk factor Q	Blood donors – Case Primary Sites	210	1	20/60	70
	Blood donors – Case peripheral sites	180	1	20/60	60
	Blood donors -Control primary sites	540	1	20/60	180
	Blood donors –Control- peripheral sites	420	1	20/60	140
	Blood donors - total	1,350	1	20/60	450

Dated: May 29, 2014.

Keith Hoots,
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Dated: May 29, 2014.

Lynn Susulske,
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